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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/007,177	12/05/2001	Stephen Craig Dyar	5962-01-CA	5683

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EXAMINER

YOUNG, MICAH PAUL

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 07/25/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/007,177

Applicant(s)

DYAR ET AL.

Examiner

Micah-Paul Young

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 contains the trademark/trade name Eudragit RS. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe ethylcellulose and polymethacrylate and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1 – 3, 8, 9, 11, 12, 17, 19, 20 – 22, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Newton (USPN 5683719). The claims are drawn to a cylindrical pharmaceutical dosage form comprising a core and a covering. The length of the cylinders is less than that of the diameter according to the claims. The formulation further comprises a matrix material. The matrix material comprises polyethylene glycol (PEG) with molecular weight between 400 and 8000. The claims recite that the formulation can be introduced into capsules, and has its core released through erosion. The claims are also drawn to a method of making the cylindrical pharmaceutical dosage form. The method comprises slicing the extruded material, and heating it to a temperature between 40°C and 200°C.

5. Newton teaches an extruded cylindrical core material with a covering that is somewhat permeable. The formulation of the reference comprises polyvinylpyrrolidone, PEG 4000 and disperses its active ingredient through the erosion of the central core. Newton teaches that its formulation can be introduced into capsules also. The reference also teaches that in a specific embodiment for human use, the length of the rods can be as low as 5 mm while the diameter can be as high as 8 mm. Though this determination of length can be chosen by a person of ordinary skill in the art to control the dosage amount, this embodiment anticipates the claim. The reference also teaches that the formulation is heated to between 55°C and 60°C (col. 3, lin. 29 – 33, lin. 57 – 67; col. 4, lin. 28 – 50; col. 5, lin. 9 – 11, lin. 30 – 35, lin. 64 – 66; examples). These disclosures render the claims anticipated.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 1 – 3, 5 – 10, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newton (USPN 5683719) in view of Pedersen et al (USPN 4572833). The claims are drawn to a pharmaceutical dosage comprising a core and a diffusion limiting covering. The dosage form is cylindrical with the ends exposing the core. The covering comprises at least ethylcellulose and polymethacrylate. The dosage form further comprises a plasticizing agent, and a matrix forming material. The claims go onto recite that the formulation can be introduced into a capsule.

As discussed above Newton anticipates many of the essential elements of the claimed invention. In addition to these teachings, Newton presents several suggestions as to its formulation. The suggestions are common in the art and are directed to the coating and core compositions. Newton suggests that cellulose derivatives such as ethylcellulose and acrylic

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polymers such as polymethylmethacrylate can be used as coating material (col. 5, lin. 7 – 10). Though applicant claims ethylcellulose and polymethacrylate as the coating agents, these excipients are well known in the art as coating agents. As seen in Pedersen et al (col.7, lin. 45 – 50) the combination of cellulose and acrylic based polymers into coating formulation is known in the art. Also the use of Eudragit product is common in the art. It is well within the level of one of ordinary skill in the art, to select appropriate coating materials, specifically cellulose and acrylic polymers for use in controlled-release formulations.

Along with the suggestion of coating materials, Newton further suggest the presence of plasticizers in the coating, again an element common the art. Newton does not specifically name the plasticizing agents of applicant, yet the reference does suggest their presence. Pedersen however, which discloses a pharmaceutical dosage form comprising a cores and a coating, specifically names triethylcitrate, dibutylsebacate, glycerin, and tributylcitrate as possible plasticizers in the coating (col. 7, lin. 55 – 60).

Another suggestion of Newton elaborated by Pedersen is that of the matrix materials. Though Newton discloses the presence of polyvinylpyrrolidone (PVP) in the matrix of the core, it does not mention polyethylene glycol (PEG) in the matrix. Though Newton discloses PEG in the composition, it is not in the matrix, yet rather in the coating. Pedersen however, teaches that the core of its dosage form comprises PEG and PVP (col. 5, lin. 63 – 67). Again these compound are well known in the art, and the selection of them for use in controlled-release dosage forms in well within the level of on of ordinary skill in the art.

With these disclosures and suggestions in mind one of ordinary skill in the art would have been motivated to follow the suggestions of Newton, and elaborations of Pedersen. A

skilled artisan would have followed the suggestion of Newton to use coatings of a cellulose and acrylic polymer base in order to properly hold and sufficiently cover the pharmaceutical core, not allowing it to degrade too fast. As elaborated by Pedersen Eudragit product would provide proper coating and protection of the core materials. A skilled artisan would have been motivated to again follow Newton's suggestion of plasticizing agents, well known in the art in order to retain the structural integrity of the core materials. Again elaborated by Pedersen, the specific plasticizers of the applicant are well known in the art. Lastly the skilled artisan would have been motivated to follow the suggestions of both Newton and Pedersen and include PEG and PVP into the core material in order to provide sufficient bulk and binding of the active ingredients. It would have been obvious to one of ordinary skill in the art, at the time of the invention to combine follow the art's suggestion and use the coating and cores preparations of Pedersen in the preparations of Newton with an expected result of a co-extruded, cylindrical rod with a coating able to retain the structural integrity of the core, which can properly bind and hold together the active ingredients. This combination would have exposed ends and would release its active-ingredients though erosion. The combination would also be introducible into a capsule.

9. Claims 1, 4, 13 – 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newton (USPN 5683719) in view of Pedersen (USPN 4572833), Bisgaier et al (USPN 5648387) and Wong et al (USPN 5565188). The claims are drawn to a pharmaceutical dosage comprising a core and a diffusion limiting covering. The dosage form is cylindrical with the ends exposing the core. The covering comprises at least ethylcellulose and polymethacrylate. The dosage form further comprises a plasticizing agent, and a matrix forming material. The active agent in the formulation is troglitazone.

As discussed above the combination of the Newton and Pedersen renders many elements of the claimed invention obvious. One deficiency of the combination is in the active ingredients. Though Pedersen suggests oral antidiabetic agents, it does not specifically name those of applicant. These substances are common in the art, especially in the art of controlled release formulations, as seen in Bisgaier (col. 12, lin. 42 – 53). Bisgaier teaches controlled-release formulation comprising cellulose derivatives and is filled into capsules. The reference uses troglitazone, a known substance, in order to tests against its own antidiabetic drug.

Another deficiency in the combination is the PEG used in the formulation. Pedersen only suggests its use, while Newton teaches the use of PEG 4000, which is too high. PEG is a common excipient in the art of controlled-release formulation, and the selection of an appropriate molecular weight is well within the level of one of ordinary skill in the art, as seen in Wong (col. 11, lin. 2 – 8). Wong teaches a controlled-release formulation of antidiabetic drugs comprising polyvinylpyrrolidone and PEG 400 (col. 4, lin. 22 – 25; col. 12, lin. 5 – 18).

With this in mind one of ordinary skill in the art would have been motivated to follow the suggestions of Newton/Pedersen as to the inclusion of antidiabetic drugs in to the formulation and substituted the troglitazone of Bisgaier in order to impart glucose affecting properties on the formulation. A skilled artisan also would have been motivated to select the PEG 400 of Wong in order have a less viscous solution to handle and process. It would have been obvious to one of ordinary skill in the art, at the time of the invention to follow the suggestions presented in the art, to use the drug of Bisgaier and the polymer of Wong with the combined formulation of Newton/Pedersen with an expected result of a less viscous co-extruded cylindrical dosage form with active agents able to increase the utilization of glucose by the body.

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10. Claims 17, 18 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newton (USPN 5683719). The claims are drawn to a method of making a pharmaceutical dosage comprising co-extruding a length of a core material, and cutting the core after drying with a laser. The cuts are made along the longitudinal, and latitudinal axis.

As discussed above Newton discloses method steps, which anticipate the claimed invention, however, Newton is deficient in other respects. Specifically Newton teaches that the rods produced are cut prior to the drying (hardening process). This however is only preferred and is not the only embodiment. Further applicant places no criticality on when the extruded material is cut. Barring a showing of criticality to the time of cutting and unexpected results from said cutting time, the claimed invention cannot be held as patentably distinct from the prior art. Also, applicant claims that the extrudes are cut with a laser. Applicant discloses that any method of cutting is sufficient for the carrying out the invention, either laser or sharp object. Applicant again places no criticality on the device used to cut these extrudes. Again barring a showing of criticality of the device used for cutting and unexpected results from said cutting device, the claimed invention cannot be held as patentably distinct from the prior art.

One of ordinary skill in the art would have been motivated to follow the procedure of Newton in order to cut the extrudes properly. It would have been obvious to one of ordinary skill in the art, at the time of the invention to follow the suggestions of Newton in order to cut the extrudes of the invention with any device and at whatever time was deemed proper for the formulation. A skilled artisan would have an expected result of a co-extruded, cylindrical dosage form, cut into swallowable dosages.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 703-308-7005. The examiner can normally be reached on M-F 7:30am-4: 30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-7648 for regular communications and 703-746-7648 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Micah-Paul Young
Examiner
Art Unit 1615

MPY
July 18, 2002


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